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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE HAR 28 PM 4: 09

é application of: Miland Moreshwar GHARPURE, et al.

Serial No.: 10/541,473

Group No.: N/A Filed: January 19, 2006 Examiner:

N/A For: A PROCESS FOR THE MANUFACTURE OF CEFPODOXIME PROXETIL

Attorney Docket No.: U 015837-4

Commissioner for Patents P.O. BOX 1450 Alexandria, Va. 22313

REFUND COMPLETED PCT NATIONAL DIVISION

Sir:

REQUEST FOR REFUND

Deposit Account 12-0425 was charged \$360.00 for claims - multiple dependent (Fee Code 1616) on January 24, 2006 (Posting Ref Txt No. 10541473).

However, a Preliminary Amendment for the multiple-dependent claims was filed upon Completion of the Filing Requirements on January 19, 2006. A copy of the Preliminary Amendment is attached to show this.

Refund of the \$360.00 by credit to Deposit Account 12-0425 is requested.

Respectfully submitted,

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CERTIFICATE OF MAILING (37 CFR 1.8a)

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Date: March \ 3, 2006



• \$130 Surcharge.

10/541473 Rec'd PCT/PTO 19 JAN 2000

• Total additional claim fee(s) for this application is \$ 360

• \$360 for multiple dependent claim surchare.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice MUST be returned with the response.

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PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY, DOCKET NO.
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PATENT TRADEMARK OFFICE

CHAPTER II

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US) (ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

PCT/15/2003/000003 TITLE OF INVENTION

6 JANUARY 2003

A PROCESS FOR THE MANUFACTURE OF CEFPODOXIME PROXETIL

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PRELIMINARY AMENDMENT

Please amend the above identified application as follows:

CERTIFICATION UNDER 37 C.F.R. 1.10*

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I hereby certify that this paper, along with any document referred to, is being deposited with the United States Postal Service on this date January 19, 2006, in an envelope as Express Mail Post Office to Addressee," mailing Label Number EV 480 463 005 US, addressed to the: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

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IN THE CLAIMS

1. (Currently Amended) A process for obtaining cefpodoxime proxetil of formula (I), of high purity conforming to pharmacopoeial specification comprising,

addition of adding a solution of methanesulfonic acid in water to a solution of impure cefpodoxime proxetil of formula (I) in an organic solvent to form the corresponding cefpodoxime proxetil methanesulfonate of formula(II¹)[[,]];

$$H_2N$$
 S
 OCH_3
 O

followed by addition of adding a co-solvent and separation separating of the aqueous phase containing comprising cefpodoxime proxetil methanesulfonate of formula (II¹) having a diastereomeric ratio of (R/R+S) between 0.5 to 0.6; and subsequent neutralization of neutralizing the methaneulfonate methanesulfonate salt (II¹) with a base to give cefpodoxime proxetil (I) free of impurities and having a diastereomeric ratio of (R/R+S) between 0.5 to 0.6 or,

addition adding of impure cefpodoxime proxetil of formula (I) to a solution of

methanesulfonate of formula (Π^1) in water,

$$H_2N$$
 S
 OCH_3
 O

- 2. (Original) A process as claimed in claim 1, wherein said pure cefpodoxime proxetil is dissolved in a water-miscible organic solvent, followed by optional treatment of the solution with activated charcoal, followed by filtration through a filter aid to remove charcoal and suspended particles and addition of water to the filtrate to precipitate out cefpodoxime proxetil (I) free of impurities and having a diastereomeric ratio of (R/R+S) between 0.5 to 0.6, which can be isolated by filtration.
- 3. (Currently Amended) A process as claimed in claim 1 or 2, wherein said first organic solvent is a water- immiscible solvent.
- 4. (Currently Amended) A process as claimed in Claim 3, wherein the water-immiscible organic solvent is selected from the group consisting of methyl acetate, ethyl acetate, butyl acetate, methyl ethyl ketone and methyl iso-butyl ketone.
- 5. (Currently Amended) A process as claimed in any preceding claim 1, wherein the co-solvent is selected from the group consisting of an aliphatic hydrocarbon, aromatic hydrocarbon and an ether.
- 6. (Currently Amended) A process as claimed in Claim 5, wherein the aliphatic

- 14. (Currently Amended) A process as claimed in any preceding claim 1, wherein the pure cefpodoxime proxetil of formula (I) after neutralization with a base is isolated by filtration.
- 15. (Currently Amended) A process as claimed in any preceding claim 1, wherein the diastereomeric ratio of (R/R+S) pure cefpodoxime proxetil of formula (I) is between 0.5 to 0.6.
- 16. (Currently Amended) A process as claimed in any one of claims claim 3 to 15, wherein the water-miscible organic solvent is selected from the group consisting of lower alcohols such as methanol, ethanol and isopropanol; lower alkyl ketones such as acetone; lower alkyl glycols ethers such as methyl glycol; dipolar aprotic solvents such as N; N-dimethylacetamide and dimethyl sulfoxide and cyclic ethers such as tetrahydrofuran and dioxane.

17. (Cancelled)

- 18. (New) A process as claimed in claim 9, wherein said methanesulfonic acid is employed in a molar ratio of between 1.0 to 2.0 mole equivalent of cefpodoxime proxetil, preferably between 1.5 to 2.0 mole equivalent.
- 19. (New) The process according to claim 16, wherein the lower alcohol is selected from the group consisting of methanol, ethanol and isopropanol.
- 20. (New) The process according to claim 16, wherein the lower alkyl ketone is acetone.

- 21. (New) The process according to claim 16, wherein the lower alkyl glycol ether is methyl glycol.
- 22. (New) The process according to claim 16, wherein the dipolar aprotic solvent is selected from the group consisting of N,N-dimethylacetamide and dimethyl sulfoxide.
- 23. (New) The process according to claim 16, wherein the cyclic ether is selected from the group consisting of tetrahydrofuran and dioxane.

REMARKS

The above amendatory action taken is solely for the purpose of avoiding claim fees that would otherwise accrue due to the presence of multiple dependent claims.

Respectfully submitted,

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